510(k) Summary

Submitter of the Application:
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FEB 1 6 2010

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Date: 02-04-10

Trade Name: Tropazone CR

Common Name: Hydrogel wound dressing

Device Classification: 21 CFR 878.4022 "Dressing, Wound, Hydrogel"
Class: Unclassified
Product Code:

Substantial Equivalence/Predicate Device: Tropazone CR is substantially equivalent to the currently marketed device Biafine cleared under application number K964240, Tropazone Lotion cleared under application number K090337, MimyX cream, cleared under application number K041342 and Zenieva, cleared under application number K073246.

Device Description: Tropazone CR is a non-sterile, semi-viscous emulsion intended for topical application. It is presented as a prescription medication, requiring a physician's diagnosis of disease state prior to use. This product is formulated as an oil-in-water emulsion containing moisturizing ingredients to keep the area moist. The oil composition of Tropazone CR is composed of mineral oil, lecithin, fatty acids and a silicon-based organic polymer.

The intended use is identical to that of Biafine, Tropazone Lotion, MimyX cream, and Zenieva.

Table 1, below, provides a technological comparison of Tropazone CR and the predicate devices.

Table 1. Technological Comparison

Product Name	Tropazone CR	Biafine	Tropazone	MimyX	Zenieva
510(k)		K964240	K090337	K041342	K073246
Ingredients	Water, liquid paraffin (mineral oil), petrolatum, alcohol, glyceryl stearate, PEG-100 stearate, paraffin, lecithin, cetyl alcohol, dimethicone, imidazolidinyl urea, triethanolamine, methylparaben, propylparaben, fragrance	Water, liquid paraffin, ethylene glycol monosterate, stearic acid, propylene glycol, paraffin wax, squalene, avocado oil, trolamine/sodium alginate, triethanolamine, cetyl palmitate, methylparaben (sodium salt) sorbic acid (potassium salt), polyparaben (sodium salt), fragrance	Water, liquid paraffin (mineral oil), petrolatum, alcohol, glyceryl stearate, PEG-100 stearate, paraffin, lecithin, polysorbate 60, DEA-cetyl phosphate, dimethicone, carbomer, imidazolidinyl urea, methylparaben, propylparaben, fragrance	Water, olive oil, glycerin, pentylene glycol, palm glycerides, vegetable oil, hydrogenated lecithin, squalene, betaine, palmitamide MEA, sarcosine, acetamide MEA, hydroxyethyl cellulose, sodium carbomer, xanthan gum	Water, olive oil, glycerin, pentylene glycol, palm glycerides, vegetable oil, hydrogenated lecithin, squalene, betaine, palmitamide MEA, sarcosine, acetamide MEA, hydroxyethyl cellulose, sodium carbomer, xanthan gum
# applications Per day	3 times per day or as needed	3 times per day or as needed	3 times per day or as needed	3 times per day or as needed	3 times per day or as needed
Claim	Tropazone CR is for the dressing and management of superficial wounds, minor abrasions, dermal ulcers, donor sites, 1st and 2nd degree burns, including sunburns and radiation dermatitis.	Biafine is for the dressing and management of superficial wounds, minor abrasions, dermal ulcers, donor sites, 1st and 2nd degree burns, including sunburns and radiation dermatitis. When applied properly to a wound, Biafine provides an optimum moist environment for	Tropazone Lotion is used to manage and relieve the burning and itching experienced with various types of dermatoses, including radiation dermatitis, atopic dermatitis, atopic dermatitis, and allergic contact dermatitis. It	MimyX is used to manage and relieve the burning and itching experienced with various types of dermatoses, including radiation dermatitis, atopic dermatitis, atopic dermatitis, and allergic contact	Zenieva is used to manage and relieve the burning and itching experienced with various types of dermatoses, including radiation dermatitis, atopic dermatitis, atopic dermatitis, and allergic contact dermatitis. It helps relieve

		the healing process and isolates the wound from harmful germs and other external contamination.	helps relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.	dermatitis. It helps relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.	dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.
Product Description	Water-based emulsion	Water-based emulsion	Water-based emulsion	Water-based emulsion	Water-based emulsion
Physical Properties	Non-sterile white to off-white cream	Non-sterile white to off-white lotion	Non-sterile white to off-white thick cream	Non-sterile white to off-white thick cream	Non-sterile white to off-white thick cream

Clinical Performance Data

Repeat Insult Patch Testing with 50 human subjects showed Tropazone CR to be a non-primary irritant and non-primary sensitizer to the skin.

Nonclinical Performance Data:

In a L929 Agar Overlay Cytotoxicity study using Tropazone CR, the cells exhibited a mild to moderate reaction, meeting the requirements of the L929 Agar Overlay Cytotoxicity Test as described in ISO 10993-5 and USP 23, Biological Reactive Tests *In-Vitro* (87).

Conclusion

Tropazone CR is substantially equivalent to Biafine and the additional predicate devices as demonstrated in Table 1 above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB 16 2010

Midlothian Laboratories
% Mr. Bryce Harvey
President
780 Industrial Park Boulevard
Unit C
Montgomery, Alabama 36117

Re: K093544
Trade/Device Name: Tropazone™ CR
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 11, 2010
Received: January 14, 2010

Dear Mr. Harvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Tropazone™ CR
Indications for Use:

Tropazone CR is for the dressing and management of superficial wounds, minor abrasions, dermal ulcers, donor sites, 1st and 2nd degree burns, including sunburns, and radiation dermatitis.

Prescription Use: X AND/OR Over-the-Counter Use: _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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510(k) Number K093544